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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,150	02/17/2004	David Munn	275.00090101	1273

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EXAMINER	
RAE, CHARLESWORTH E	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,150	MUNN ET AL.	
	Examiner	Art Unit	
	Charleswort Rae	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-47 are currently pending and are the subject of this Office Action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-26, drawn to a method of augmenting rejection of cells by a subject comprising administering to the subject an effective amount of a pharmaceutical composition comprising a D isomer of an inhibitor of indoleamine-2,3-dioxygenase, classified in class 514, subclass 6, 419, 109. If this Group is elected, then the below summarized Species Election is also required.

II. Claim 27, drawn to a method of stimulating an immune response comprising administering and effective amount of a pharmaceutical composition comprising a D isomer of an inhibitor of indoleamine-2,3-dioxygenase, classified in class 514, subclass 6, 419, 109. If this Group is elected, then the below summarized Species Election is also required.

III. Claim 28, drawn to a method of enhancing the signal in a mixed leukocyte response (MLR) comprising adding an effective amount of a D isomer of an inhibitor of indoleamine-2,3-dioxygenase, classified in class 514, subclass 6. If this Group is elected, then the below summarized Species Election is also required.

IV. Claim 29, drawn to a method of increasing T cell activation by an antigen-presenting cell comprising administering an effective amount of a pharmaceutical composition comprising a D isomer of an inhibitor of indoleamine-2,3-dioxygenase, classified in class 424, subclass 6, 93.2,69.2, 419, 109, 283, 263.1. If this Group is elected, then the below summarized Species Election is also required.

V. Claim 30, drawn to a method of reversing the immunosuppressed state in a subject with HIV comprising administering to the subject an effective amount of a pharmaceutical composition comprising a D isomer of an inhibitor of indoleamine-2,3-dioxygenase, classified in class 514, subclass 6, 93.2, 69.2, 419, 109, 283, 263.1. If this Group is elected, then the below summarized Species Election is also required.

VI. Claims 31-37, drawn to a method of treating a subject with an infection comprising administering to the subject an effective amount of a pharmaceutical composition comprising a D isomer of an inhibitor of indoleamine-2,3-dioxygenase, classified in class 514, subclass 6. If this Group is elected, then the below summarized Species Election is also required.

VII. Claims 38 and 40, drawn to a method of reducing immunosuppression in a subject wherein said immunosuppression is mediated by an antigen presenting cell, and wherein said presenting cell expresses indoleamine-2,3-dioxygenase (IDO), the method comprising administering to the

subject an effective amount of a pharmaceutical composition comprising a D isomer of an inhibitor of indoleamine-2,3-dioxygenase, classified in class 514, subclass 6. If this Group is elected, then the below summarized Species Election is also required.

VIII. Claims 39 and 41, drawn to a method of preventing the development of immunosuppression in a subject, wherein said immunosuppression is mediated by an antigen presenting cell, and wherein said antigen presenting cell expresses the indoleamine-2,3-dioxygenase (IDO), the method comprising administering to the subject an effective amount of a pharmaceutical composition comprising a D isomer of an inhibitor of indoleamine-2,3-dioxygenase, classified in class 514, subclass 6. If this Group is elected, then the below summarized Species Election is also required.

IX. Claim 42, drawn to a method of delaying the relapse or progression of a tumor in a subject, the method comprising administering an effective amount of a pharmaceutical composition comprising a D isomer of an inhibitor of indoleamine-2,3-dioxygenase, classified in class 514, subclass 69.2, 419, 109, 283, 263.1. If this Group is elected, then the below summarized Species Election is also required.

X. Claim 43, drawn to a method of treating a subject suffering from a neoplastic condition, the method comprising administering to the subject an effective amount of a pharmaceutical composition comprising a D

isomer of an inhibitor of indoleamine-2,3-dioxygenase, classified in class 514, subclass 6. If this Group is elected, then the below summarized Species Election is also required.

XI. Claim 44-47, drawn to a pharmaceutical composition comprising a D isomer of an inhibitor of indoleamine-2,3-dioxygenase and at least one additional therapeutic agent, classified in class 514, subclass 6. If this Group is elected, then the below summarized Species Election is also required.

Inventions I- X are directed to related methods of using a D isomer of an inhibitor of indoleamine-2,3-dioxygenase. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct because the inventions are either not capable of use together or can have a materially different design, mode of operation, function in view of their divergent subject matter. Specifically, Invention I is directed towards a method of augmenting rejection of cells; Invention II is directed towards a method of stimulating an immune response; Invention III is directed towards a method of enhancing the signal in a mixed leukocyte response (MLR); Invention IV is directed towards a method of increasing T cell activation by an antigen-presenting cell; Invention V is directed towards a method of reversing the immunosuppressed state in a subject with HIV; Invention VI is directed

towards a method of treating a subject with an infection; Invention VII is directed towards a method of reducing immunosuppression in a subject; Invention VIII is directed towards a method of preventing the development of immunosuppression; Invention IX is directed towards a method of delaying the relapse or progression of a tumor in a subject; and Invention X is directed towards a method of treating a subject suffering from a neoplastic condition. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Invention XI and Inventions I-X are related as product and process of use. The invention XI and inventions I-X can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product as evidenced by the fact that Groups I-X are different methods of practicing the invention of Group XI. Further, it is reasonable to believe that the product as claimed by Group XI could be used in an *in vitro* method for evaluating the presence or absence of indoleamine-2,3-dioxygenase.

Because inventions I-XI are independent or distinct for the reasons given above coupled with the fact that a search is required for each group, restriction for examination purposes is proper. While Groups I-XI can be identically classified under U.S. Patent Classification guidelines, to search them together would present an undue search

burden on the Examiner due to the extensive databases of patent and non-patent literature that would have to be searched in view of the divergent subject matter encompassed by the different groups. Thus, Groups I-XI have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Election of Species regarding Groups I-XI

This application contains claims directed to more than one species of the generic Inventions that would require an unduly extensive and burdensome search by the examiner if all the claimed species were examined together.

For example, inventions I-XI encompass multiple species of D-isomer of an inhibitor of indoleamine-2,3-dioxygenase, including the following: a1) 1-methyl-D-tryptophan, a2) β-(3-benzofuranyl)-D-alanine, a3) β-(3-benzo(b)thienyl)-D-alanine, a4) 6-nitro-D-tryptophan, and a5) 1-methyl-D-tryptophan. Each species represent a different chemical structure. The species are independent or distinct because they represent different chemical compounds. In view of the undue search burden that will be created by the multiplicity of chemical compounds encompassed by these claims, applicant is required to elect one single species of a D-isomer of an inhibitor of indoleamine-2,3-dioxygenase for examination purposes.

Further, the pharmaceutical composition and method of using the pharmaceutical composition encompass multiple subcombinations comprising a D-isomer of an inhibitor of indoleamine-2,3-dioxygenase alone or in combination with other additional therapeutic modalities. Applicant is required to elect:

A) Claim embodiments with a D-isomer of an inhibitor of indoleamine-2,3-dioxygenase alone,

B) Claim embodiments with said D-isomer in combination with other therapeutic modalities. Then, if B) is elected, applicant is further required to elect a single species from a list below of additional agent(s) or therapeutic modalities, except that applicant may elect one or more chemotherapeutic agents from the "a" list if the species are chemotherapeutic agents:

a) chemotherapeutic agent(s), including 1) cyclophosphamide, 2) methotrexate, 3) fluorouracil, 4) doxorubicin, 5) vincristine, 6) ifosfamide, 7) cisplatin, 8) gemcytabine, 9) busulfan, 10) ara-C, and 11) combinations thereof, e.g. cyclophosphamide alone, or cyclophasphamide and cisplatin, or

b1) radiation therapy, b2) total body irradiation, e.g. total body irradiation = b2, or

c) a cytokine, including 1) GM-CSF or 2) flt-3-ligand, e.g. GM-CSF = c1; or

d) a vaccine, including 1) a specific tumor vaccine comprising non-genetically modified tumor cells e.g. melanoma, or 2) a specific tumor vaccine comprising genetically modified tumor cells, or 3) a specific anti-viral vaccine e.g. anti-HIV, or 4) a specific anti-bacterial vaccine e.g anti-tuberculosis vaccine.

Additional Election of Species regarding Groups I, IV, V, VI, VII, VIII, IX, X

Inventions I, and IV-X encompass multiple different species of cell types, including:

a1) melanoma tumor cells, a2) colon cancer cells, a3) pancreatic cancer cells, a4) breast cancer cells, a5) prostate cancer cells, a6) lung cancer cells, a7) leukemia

cells, a8) brain tumor cells, a9) lymphoma cells, a10) sarcoma cells, a11) ovarian cancer cells, a12) Kaposi's sarcoma cells,

b) cells infected with a virus, including the following:

1) human immunodeficiency virus, 2) cytomegalovirus,

c) cells infected with an intracellular parasite, including the following:

1) Leishmania donovani, 2) Leishmania tropica, 3) Leishmania major, 4) Leishmania aethiopica, 5) Leishmania Mexican, 6) Plasmodium falciparum, 7) Plasmodium viva, 8) Plasmodium ovale, 9) or Plasmodium malariae,

d) intracellular bacteria, including the following:

1) Mycobacterium leprae, 2) Mycobacterium tuberculosis, 3) Listeria monocytogenes, and 4) Toxplasma gondii.

The above species are distinct as they represent different morphologic and pathogenic cells. For example, cancer cells possess different morphologic characteristics; viral cells possess different virologic effects; intracellular parasites possess different parasitic effects; and intracellular bacteria possess different microbacterial effects. The divergent subject matter, coupled with the fact that the species have acquired a different status in the art, creates a search burden on the examiner. In view of the undue search burden that will be created by the multiplicity of tumor, viral, and bacterial cells encompassed by these claims, applicant is required to elect one single specific cell type from any one of the above list of cell types for examination purposes.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed disease state for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 27, 28, 29, 30, 31, 38, 39, 42, 43, and 44 are considered generic to the above listed species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

13 November 2006
CER

Ardin H Marschel 11/17/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER